In the Office action of September 11, 2002, Paper No. 22, claims 1-6,10-13,15,16,19-22,25-30,36, and 46-55 were pending with claims 7-9,14,17,18,23,24,31-35 and 42-45 having been withdrawn from consideration. Claims 1,2,4,5,10-12,15,16,19-22,25-30,36, and 46-55 are rejected. Claims 6 and 13 are objected to. In particular, claims 36 was rejected under 35 U.S.C. 112, first paragraph, because the Examiner decided that the best mode contemplated by the inventor has not been disclosed. Claims 2,11,19-22,25-30, and 46-54 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 19,28,36, and 48 are rejected under U.S.C. 102(b) as being anticipated by Boretos et al. Claims 19,28,36, and 48 are rejected under U.S.C. 102(b) as being anticipated by Reul. Claim 36 is rejected under U.S.C. 102(b) as being anticipated by Cox. Claims 36,50-54, and rejected under U.S.C. 102(e) as being anticipated by Bessler et al. Claims 1,2,4,5,12,36, and 50-54 are rejected under U.S.C. 102(e) as being anticipated by Moll et. al. Claims 20-22 and 49 are rejected under U.S.C. 103(a) as being unpatentable over Boretos et al. in view of Bessler. Claims 25-27 are rejected under U.S.C. 103(a) as being unpatentable over Boretos et al. in view of Cox. Claims 47 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler in view of Cox. Claims 10,11,46,47, and 55 are rejected under 103(a) as being unpatentable over Moll et al. in view of Cox. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. in view of Bessler et al.

Claim Objections

With regard to point a of the Claim Objections, claims 4 and 5 are being amended such that they both depend from claim 1. With regard to point b, claim 36 is now withdrawn and thus, the objection will not be addressed. With regard to point c, claim 46, is being withdrawn although Applicants disagree that 'therearound' is an improper word. Point d is also rendered moot by the cancellation of claim 50. With regard to point e, the appropriate correction to

claim 55 is made. Applicants' response to the Examiner's other points are found below.

Claim Rejections 35 USC § 112

Examiner's Point 4:

Although claim 36 is being withdrawn by this response, Applicants feel compelled to point out that the 'best mode' rejection based on U.S.C. 35 112, first paragraph is improper with respect to any of the claims. The Examiner is referred to section 2165.03 of the M.P.E.P. which states the requirements for rejection due to lack of best mode. In it, the examiner is instructed to assume best mode is disclosed 'unless there is evidence presented that is inconsistent with that assumption.' The requirement is for the best mode to be 'disclosed in the application'. The best mode need not be designated and there certainly is no requirement that every element of the Applicant's working example of the best mode be set forth in the claims. We maintain that claim 36 distinctly and particularly claims the invention in part by calling for 'a first arcuate outer edge [of a leaflet] that exerts pressure against, and at least forms a partial seal with, a vascular wall.' Even so, the argument whether or not the support structure or frame should be positively recited in the claim has nothing to do with whether or not the best mode is or is not part of the specification. There is no attempt by the Applicants to conceal the best mode – it is fully described in the application – and the Examiner cannot possess any evidence that the best mode was indeed omitted from the written specification and drawings.

Examiner's Point 6:

Regarding points 6a-b, 'vascular valve' has been replaced with 'implantable valve' and 'free edge' has been replaced with 'inner edge' in claim 2, thereby correcting the respective antecedent problems. Regarding point 6c, Claim 11 is amended to properly depend on Claim 10. Points 6d-i are now moot as these claims are being withdrawn.

Not correct

Claim Rejections 35 USC § 102

Examiner's Points 8-11:

Claims 19,28,36, 48, and 50-54 are being withdrawn from consideration.

Examiners' Point 12:

Claim 1 stands rejected under 35 U.S.C. 102(e) based upon the assertion that it is anticipated by U.S. Patent No. 6,287,334 (Moll et al.). This rejection is respectfully traversed for the following reasons.

The legal standard for anticipation requires that the reference expressly or inherently teach each and every element of the claim. Where the Patent Office intends to rely upon inherent teachings of a reference, the features relied upon must necessarily be present in the reference. Mere possibilities will not suffice. Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." Cont'l Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749(Fed. Cir. 1991). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599(Fed. Cir. 2002) (quoting In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

Claim 1 includes the feature "the outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements and thereby adapted to engage the wall of the bodily passage". Moll et al. does not expressly teach anything concerning this feature, and therefore it is assumed that the Office Action's rejection was made based upon the position that this feature is inherent in the Moll et al. teachings. However, in its

specification, Moll et al. only teaches that the "[b]lood flow stoppage elements 6, having the form of flexible hollow cones, are each supported on a substantially triangular frame section 8 of a support 10. . . ". Similarly, in its Figures, Moll et al. lacks any illustration of this claimed feature (see in particular Figure 1). Accordingly, there is no express or inherent teaching of each and every element of claim 1 in the Moll et al. patent. Withdrawal of the rejection of claim 1 and its dependent claims 2, 4, 5 and 12 under 35 U.S.C. 102(e) over Moll et al. is therefore solicited.

Claim Rejections 35 USC § 103

Examiner's Points 14 and 15:

Claims 20-22, 25-27, and 49 are now cancelled from this application so there is no need to address the Examiner's reasons for rejection at this time.

Examiner's Point 16:

Claim 55 (and now-cancelled claim 47) stands rejected under 35 USC 103(a) based upon the assertion that it is unpatentable over U.S. Patent No. 5,855,601 (Bessler et al.) in view of U.S. Patent No. 5,713,950 (Cox). This rejection is respectfully traversed because even assuming these two references are combinable as asserted in the Office Action, they clearly fail to teach or suggest elements of the claim.

In support of this rejection, the Office Action takes the position that "Bessler et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa". This position is not correct. Claim 55 includes the feature of "the outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements and thereby adapted to engage the wall of the bodily passage". This feature is not taught in Bessler et al., which only teaches that "[t]he cuff portion is attached to the stent by sutures 38". See Col. 5, lines 41-42 and Figures showing single-point attachment of the cuff to straight sections 33 by sutures 38.

Nor is there any motivation provided within Bessler et al. to modify its device to meet the claimed feature. To the contrary, Bessler et al. describes their device to be functional in the fashion they desire, as shown.

Looking to the Cox reference, there are absolutely no teachings to supplement the above-noted shortcomings of Bessler et al. In fact, Cox only teaches the use of a stent in conjunction with an otherwise implanted valve, wherein the stent "could be secured within the aortic wall 250, outside of the SIS segment 200. This type of stent, if used, would containing [sic] projections which extend in an inward radial direction, toward the central axis of the aorta. These projections, which would be positioned at the midpoints between the three attachment points at the outlet end, would prevent any flattening of the cusp regions 222 against the interior of aortic wall 250." See Col. 24, lines 3-17. Accordingly, Cox does not teach any attachment of the valve material to the stent as claimed, and thus cannot in any way supplement the teachings of Bessler et al. in a manner to render the present claims obvious.

For the above reasons, the rejection of claim 55 under 35 U.S.C. 103(a) over the combination of Bessler et al. and Cox is overcome, and its withdrawal is solicited.

Examiner's Point 17:

Claim 55 stands rejected under 35 USC 103(a) based upon the assertion that it is unpatentable over U.S. Patent No. 6,287,334 (Moll et al.) in view of U.S. Patent No. 5,713,950 (Cox). This rejection is also respectfully traversed, because even assuming these two references are combinable as asserted in the Office Action, they clearly fail to teach or suggest elements of the claim.

In support of this rejection, the Office Action takes the position that "Moll et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa". For reasons similar to those set forth above in the analysis of the Bessler et al./Cox rejection, this position is not correct. Claim 55 includes the feature of "the outer edge of each one of the plurality of leaflets attached along one side element of said

plurality of side elements and thereby adapted to engage the wall of the bodily passage". This feature is not taught in Moll et al., , which only teaches that the "[b]lood flow stoppage elements 6, having the form of flexible hollow cones, are each supported on a substantially triangular frame section 8 of a support 10Y". Similarly, in its Figures, the Moll et al. patent lacks any illustration of this claimed feature (see in particular Figure 1). Nor is there any motivation provided within Moll et al. to modify its device to meet the claimed feature. To the contrary, Moll et al. describe their device to be functional in the fashion they desire, as shown.

Looking again to the Cox reference, there are absolutely no teachings to supplement the above-noted shortcomings of Moll et al. In fact, Cox only teaches the use of a stent in conjunction with an otherwise implanted valve, wherein the stent "could be secured within the aortic wall 250, outside of the SIS segment 200. This type of stent, if used, would containing [sic] projections which extend in an inward radial direction, toward the central axis of the aorta. These projections, which would be positioned at the midpoints between the three attachment points at the outlet end, would prevent any flattening of the cusp regions 222 against the interior of aortic wall 250." See Col. 24, lines 3-17. Accordingly, Cox does not teach or suggest any attachment of the valve material to the stent as claimed, and thus cannot in any way supplement the teachings of Moll et al. in a manner to render the present claims obvious.

For the above reasons, the rejection of claims 55 under 35 U.S.C. 103(a) over the combination of Moll et al. and Cox is overcome, and its withdrawal is solicited.

Claims 46 and 47 are being withdrawn from consideration. As for claim 10 and 11, the same arguments apply which are presented above for claim 55. The rejection of claims 10 and 11 as being unpatentable (35 USC 103(a)) over Moll et al. in view of Cox is overcome because the references, even if combinable, do not teach or suggest the elements of the claims. For example, neither reference discloses the claim 1 limitation of the outer leaflet edges being "attached along one side element of said plurality of side elements and thereby adapted to engage the wall of the bodily passage in said path extending at least

partially longitudinally and at least partially circumferentially such that the leaflet extends along said bodily passage away from the inner edges in said second direction." Therefore, we respectfully ask that the Examiner withdraw the rejection of claims 10 and 11.

Examiner's Point 18:

Claims 15 and 16 stands rejected under 35 USC 103(a) based upon the assertion that it is unpatentable over U.S. Patent No. 6,287,334 (Moll et al.) in view of U.S. Patent No. 5,855,601 (Bessler et al.) This rejection is respectfully traversed, because the references, even if combinable, do not teach or suggest the elements of the claims.

Applicants again present the argument that claim 1 (from which these claims depend), requires that the leaflet edges be "attached along one side element of said plurality of side elements and thereby adapted to engage the wall of the bodily passage. . . ". This wall-engaging outer leaflet edge that is attached along the (frame) side elements is not taught by either the Moll or Bessler reference. Therefore, the rejection is overcome, and we request that the claims be allowed.

Allowable Subject Matter

The indications of allowable subject matter given in paragraphs 21 and 22 of the Office Action are acknowledged with appreciation. In response, claims 29 and 30 have been rewritten as new claims 58 and 59 in a fashion that overcomes the rejections under 35 U.S.C. 112 and includes all of the limitations of the base claim and any intervening claims. Favorable action on claims 58 and 59 is thus solicited. Claims 6 and 13 have not been rewritten as new claims. For the reasons discussed above in conjunction with independent claim 1 from which they depend, these claims are believed to be allowable in their present, dependent form. Favorable consideration of claims 6 and 13 as presently pending is thus also requested.

Serial No. 09/777,091

PATENT

Summary

By this action, claim 1-2, 4-6, 10-13, 15-16, and 55-59 are now pending in the application. Claims , claims 56-59 are being added. In order to expedite the examination and allowance of the present application, claims 7-9, 14, 17-36, and 46-54 are being withdrawn from consideration. This action should not be interpreted as an acknowledgment of the merits of the Examiner's position regarding any of the withdrawn claims. The reexamination and reconsideration of the remaining claims of this application is respectfully requested, and it is further requested that the application be passed to issue. Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' representative requests a telephone interview with the Examiner, if so necessary, to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

Dusan Pavcnik
Frederick S. Keller
Josef Rosch
Thomas A. Osborne
John A. DeFord
Brian L. Bates
Christopher G. Dixon
Andrew K. Hoffa
Raymond B. Leonard II
Joseph F. Obermiller

Date: Nov 10, 2003

By _____
Charles W. Agnew, Patent Agent
Reg. No. 44,497
(812) 330-1824

MARKED-UP CLAIMS

1. (Previously Amended) An implantable valve for a bodily passage of tubular shape, comprising:

a support frame configured for expansion to conform to a wall of the bodily passage, said support frame when expanded providing a plurality of side elements each defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall,

a plurality of leaflets, each leaflet thereof having a body extending from a wall-engaging outer edge to an inner edge proximate a corresponding inner edge of at least one other leaflet of the plurality of leaflets,

the inner edges of said plurality of leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along the bodily passage, and further cooperable to engage each other sufficiently to restrict fluid flow in a second direction opposing the first direction,

the outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements and thereby adapted to engage the wall of the bodily passage in said path extending at least partially longitudinally and at least partially circumferentially such that the leaflet extends along said bodily passage away from the inner edges in said second direction.

2. (Currently Amended) The ~~vascular~~ implantable valve of claim 1, wherein at least a portion of the body of the leaflet being flexible at least proximate the ~~free~~ inner edge thereof.

3. (Canceled)

4. (Currently Amended) The implantable valve of claim ~~3~~ 1 wherein the outer edges of the plurality of leaflets include overhanging material, the overhanging material extending beyond the frame to which the plurality of leaflets are attached.

5. (Currently Amended) The implantable valve of claim ~~3~~ 1 wherein said frame comprises wire to and around which the bodies of the leaflets are secured.

6. (Previously Amended) The implantable valve of claim 1 wherein the plurality of leaflets includes two leaflets such that when the frame is substantially flattened, it assumes a diamond shape with the inner edges of the two leaflets defining a slit therebetween.

7. (Original) The implantable valve of claim 3 wherein the body and the frame of each leaflet comprises an integral, one-piece member.

8. (Original) The implantable valve of claim 1 wherein said integral, one-piece member is molded into a generally flat shape.

9. (Original) The implantable valve of claim 7 wherein said integral, one-piece member is molded into a serpentine shape.

10. (Amended) The implantable valve of claim 1 wherein the plurality of leaflets comprises an extracellular collagen matrix.

11. (Original) The implantable valve of claim ~~6~~ 10 wherein the extracellular collagen matrix includes small intestinal submucosa.

12. (Original) The implantable valve of claim 1 comprising two leaflets.

13. (Original) The implantable valve of claim 1 wherein the frame is adapted to assume a plurality of configurations, the plurality of configurations includes a generally flat configuration, whereby the frame in the generally flat configuration is generally diamond-shaped.

14. (Cancelled)

15. (Original) The implantable valve of claim 1 further including at least one barb to anchor the implantable valve to the wall of the bodily passage.

16. (Original) The implantable valve of Claim 15 wherein the at least one barb is integral projection extending from the frame.

17 - 54 (Canceled)

55. (Currently Amended) An implantable valve for a bodily passage of tubular shape, comprising:

a support frame configured for expansion to conform to a wall of the bodily passage, said support frame when expanded providing a plurality of side elements each defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall,

a plurality of leaflets comprising an extracellular collagen matrix material, each leaflet thereof having a body extending from a wall-engaging outer edge to an inner edge proximate a corresponding inner edge of at least one other leaflet of the plurality of leaflets,

the inner edges of said plurality of leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along the bodily passage, and further cooperable to engage each other sufficiently to restrict fluid flow in a second direction opposing the first direction,

the outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements and thereby adapted to directly engage the wall of the bodily passage therearound and provide ingrowth of adjacent native tissue into the extracellular collagen matrix material.

56. (New) The implantable valve of claim 55 wherein the collagen matrix material comprises submucosal tissue.

57. (New) The implantable valve of claim 55 wherein the collagen matrix material comprises small intestinal submucosa.

58. (New) An implantable valve for a bodily passage of tubular shape, comprising:

a frame that includes a plurality of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and extending in an opposite direction therefrom, each of the plurality of legs terminating at a second end of the implantable valve opposite the first end such that the plurality of legs generally assume a serpentine configuration along the circumference of a bodily passage when situated therein,

a plurality of leaflets, each leaflet comprising a covering that includes one or more flexible materials, the leaflet including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by one of the plurality of legs, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage,

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated

therein and being configured such that the leaflet is cooperable with at least one other leaflet to define an opening that permits positive flow of fluid therethrough in a first direction, while the plurality of leaflets are further adapted to trap between the leaflets and the inner wall of the bodily passage fluid flowing in a second direction opposite the first direction and seal against one another to restrict fluid flow in said second direction; and

wherein the frame is adapted to assume a plurality of configurations, a first configuration of the plurality of configurations being a generally flat plane.

59. (New) An implantable valve for a bodily passage of tubular shape, comprising:

a frame that includes a plurality of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and extending in an opposite direction therefrom, each of the plurality of legs terminating at a second end of the implantable valve opposite the first end such that the plurality of legs generally assume a serpentine configuration along the circumference of a bodily passage when situated therein,

a plurality of leaflets, each leaflet comprising a covering that includes one or more flexible materials, the leaflet including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by one of the plurality of legs, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage,

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated therein and being configured such that the leaflet is cooperable with at

least one other leaflet to define an opening that permits positive flow of fluid therethrough in a first direction, while the plurality of leaflets are further adapted to trap between the leaflets and the inner wall of the bodily passage fluid flowing in a second direction opposite the first direction and seal against one another to restrict fluid flow in said second direction; and

wherein the frame is adapted to assume a plurality of configurations, a first configuration of the plurality of configurations being a generally flat plane; and

wherein the covering includes two leaflets such that when the frame in the generally flat configuration generally assumes a diamond shape with the inner edges of the two leaflets defining a slit therebetween.